MAR 2 0 2002

Attachment #2

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K011688

1. **Submitter's Identification:**

PelvicFlex Inc.
7350 South Tamiami
Trail Suite 215
Sarasota, Florida 34231

Date Summary Prepared: May 23, 2001

Contact Person: Mr. Richard C. Blackford
Tel #: 941-650-2740
Fax #: 941-484-0149
Email: richard@pelvicflex.com

2. **Name of the Device:**

PelvicFlexer Exercise Device

3. **Predicate Device Information:**

Pelvic Muscle Therapy, Colonial Medical Supply, Las Vegas, Nevada, K# 002830

4. **Device Description:**

The PelvicFlexer is a comprehensive, behaviorally based program designed for independent use by incontinence people at home. The program includes a PelvicFlexer device, instructional manual and direct support via phone and internet. The PelvicFlexer is hand-held and inserted into the vagina. The strength of the muscle contraction is reflected by the stainless steel springs.

5. **Intended Use:**

The Pelvic*Flexer* is intended to assist women in peforming Kegel Exercises which may help control stress urinary incontinence.

6. **Comparison to Predicate Devices:**

Please refer to the attached "Table of Substantial Equivalence Comparison Chart".

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

A. The Pelvic*Flexer* system was designed and tested to meet the following standards:

ISO 10993 Biocompatibility evaluation of medical device. Extensive biocompatibility and safety testing of the material used in the device was performed by NAMSA. The following tests were performed:

- ISO 10993
  - Cytotoxicity Using ISO Elution Method
  - Muscle Implantation Test (7 day)
  - Acute Systemic Toxicity
- Delayed Contact Sensitization (Maximization Method)
- Hemolysis Test (USP)
  - Direct Contact Method
  - Extraction Method

B. Safety Testing (spring load testing) to assure safety and effectiveness.

8. **Discussion of Clinical Tests Performed:**

Not applicable

9. **Conclusions:**

The Pelvic*Flexer* Exercise Device has the same intended use and similar characteristics as the predicate device, Pelvic Muscle Therapy, Colonial Medical Supply. Moreover, biocompatibility and bench testing contained in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Pelvic*Flexer* Exercise Device is substantially equivalent to the predicate device.

TABLE OF SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Category	Pelvic*Flex* Inc. Pelvic*Flexer*	Colonial Medical Supply Pelvic Muscle Therapy K# 002830
Common of usual name	Pelvic Muscle Exerciser	Pelvic Muscle Exerciser
Classification Name	884.1425 Perineometer	884.1425 Perineometer
Product Code	85 HIR	85 HIR
Intended Use Indications	Treatment of stress and /or Urge incontinence in women	Treatment of stress and / or Urge incontinence in women
Prescription Use	NO	NO

Feature	Pelvic*Flex* Inc. Pelvic*Flexer*	Colonial Medical Supply Pelvic Muscle Therapy
Target Population	Women with mild incontinence	Women with mild incontinence
Single Patient Device	YES	YES
Single User of Reusable	Reusable	Reusable
Requires Medical visits to Medical Personnel	No	NO
Sterilization Status	Clean, but not sterile	Clean, but not sterile
Biofeedback display information	NO	Numerical response to muscle contraction strength
Material Device	YES	NO
Material Sensor	No	Medical grade silicone (polydmethylsiloxane)
Biocompatibility	Guidelines set forth in ISO 10993 testing results indicated material is Biocompatible, nontoxic and well tolerated by mucosal membranes	Guidelines set forth in ISO 10993 testing results indicated material is Biocompatible, nontoxic and well tolerated by mucosal membranes
Chemical Safety	Address by biocompatibility testing (ISO 10993)	Address by biocompatibility testing (ISO 10993)
Number of models	One (Female)	One (Female)
Anatomical Sites	Vagina	Vagina
Instructions	Patient Instruction manual for home use	Patient Instruction for home use Video and manual
Stainless Steel Spring	302 A313	NO
Packaging	Device in sealed plastic bag and manual in card board box	Sensors in sealed Monitor, Video, manual in card board box

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

PelvicFlex, Inc
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K011688
Trade/Device Name: PelvicFlexer Exercise Device
Regulation Number: 21 CFR §884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: 85 HIR
Dated: December 17, 2001
Received: December 20, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment #1

510(k) Number (if known): K011688

Device Name: Pelvic/Flexer Exercise Device

Indications For Use:

The Pelvic/Flexer is intended to assist women in performing Kegel Exercises which may help control stress urinary incontinence.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓
(Optional Format 1-2-96)

Donald A. Gazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011688